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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,601

08/11/2006

Hans-Arne Hansson

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EXAMINER

DUTT, ADITI

ART UNIT

PAPER NUMBER

1649

NOTIFICATION DATE

DELIVERY MODE

05/05/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/573,601	<b>Applicant(s)</b> HANSSON ET AL.	
	<b>Examiner</b> Aditi Dutt	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-5, 16 and 20-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 3-5, 16 and 20-42 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 3-5, drawn to a method of treating and/or preventing a condition associated with loss or gain of nervous tissue administering an antiseecretory protein inducing food.

Group II, claim(s) 16, drawn to a method of inducing the formation of an antiseecretory protein comprising administering a food or a solution made from malted cereal.

Group III, claim(s) 20-22, 36, 37, drawn to a method of propagating, inducing and/or maintaining the genesis of an isolated stem cell progeny in vitro, by treating the isolated cell with an antiseecretory protein, or an oligo or polypeptide derivatives thereof, comprising Formula I.

Group IV, claim(s) 23-35, 41-42, drawn to a method of treatment or prevention of a condition associated with a gain or loss of nervous tissue, comprising administering an effective amount of an antiseecretory protein or an oligopeptide thereof, comprising Formula I.

Group V, claim(s) 38, 40, drawn to a method of propagating, inducing and/or maintaining the genesis of an isolated stem cell progeny from a germinal layer from a patient, administering an effective amount of an antiseecretory protein, or an oligo or polypeptide derivatives thereof, comprising Formula I to said patient, isolating and propagating the isolated stem cell in vitro, and transplanting said propagated cells into the same or another patient.

Group VI, claim(s) 39, drawn to a method of propagating, inducing and/or maintaining the genesis of an isolated stem cell progeny from a germinal layer from a patient, comprising isolating said cell or stem cell progeny from the patient, administering an

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effective amount of an antiseecretory protein, or an oligo or polypeptide derivatives thereof, comprising Formula I to said isolated cells and propagating the cells in vitro, and transplanting said propagated cells into the same or another patient.

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the special technical feature of a method treating and/or preventing a condition associated with loss or gain of nervous tissue administering an antiseecretory protein inducing food, which is not required by the other methods of Groups II-VI. Claim 1 is anticipated by prior art. Lange et al. (International Publication application number WO 00/38535, published 6 July 2000) teach the use of a natural antiseecretory protein for the treatment and prophylaxis of diseases caused by extreme fluid discharge (abstract). The reference also teaches that the antiseecretory protein is present in eggs, and that following the consumption of such antiseecretory protein enriched food, the antiseecretory protein levels in the human blood are elevated (page 5, lines 21-27). Since the reference teaches the same method steps as recited in claim 1, the reference inherently anticipates the treatment or prevention of various diseases including that characterized by the gain or loss of nervous tissue. Therefore, claim 1 lacks a special technical feature and cannot share one with the other claims.

Group II recites the special technical feature of inducing the formation of an antiseecretory protein comprising administering a food or a solution made from malted cereal, which is not required by the other methods of Groups I, and III-VI.

Group III recites the special technical feature of propagating, inducing and/or maintaining the genesis of an isolated stem cell progeny in vitro, by treating the isolated cell with an antiseecretory protein, or an oligo or polypeptide derivatives thereof, comprising Formula I, which is not required by the other methods of Groups I-II, and IV-VI.

Group IV recites the special technical feature of treatment or prevention of a condition associated with a gain or loss of nervous tissue, comprising administering an effective amount of an antiseecretory protein or an oligopeptide thereof, comprising Formula I, which is not required by the other methods of Groups I-III, V-VI.

Group V recites the special technical feature of propagating, inducing and/or maintaining the genesis of an isolated stem cell progeny from a germinal layer from a patient, administering an effective amount of an antiseecretory protein, or an oligo or polypeptide derivatives thereof, comprising Formula I to said patient, isolating and propagating the isolated stem cell in vitro, and transplanting said propagated cells into

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the same or another patient, which is not required by the other methods of Groups I-IV and VI.

Group VI recites the special technical feature of propagating, inducing and/or maintaining the genesis of an isolated stem cell progeny from a germinal layer from a patient, comprising isolating said cell or stem cell progeny from the patient, administering an effective amount of an antiseecretory protein, or an oligo or polypeptide derivatives thereof, comprising Formula I to said isolated cells and propagating the cells in vitro, and transplanting said propagated cells into the same or another patient, which is not required by the other methods of Groups I-V.

### 3. Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

#### A) Loss or Gain of Cell type/nervous tissue

Claims 3-5, 23, 26-29 are deemed to correspond to the species listed above in the following manner:

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above cell types have different regulatory processes controlled by different signals from different factors, exhibiting different physiology and pathology. For example, the special technical feature of oligodendroglial cell is not shared by the other species.

B) Condition

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a) Caused by damage to the central nervous system (CNS)
- b) Caused by defect to the CNS

The claims are deemed to correspond to the species listed above in the following manner: Claims 30, 31

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above disorders have distinct pathology, resulting from trauma, or acute or chronic dysfunction, and the treatment would involve varying levels of success. For example, the special technical feature of conditions caused by damage to the CNS is not shared by the conditions caused by defect of the CNS.

C) Conditions caused by damage to the CNS

The species are as follows:

Condition caused by axonal damage caused by concussion.....damage to the spinal cord after trauma

(Please refer to claim 32, 34 for a complete list).

**If applicant elected the ‘Conditions caused by damage to the CNS’ group as the species of Condition, applicant is further required to select a more specific Condition caused by damage to the CNS.**

The claims are deemed to correspond to the species listed above in the following manner: Claims 32, 34

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above diseases have distinct pathology and the treatment or tissue repair would involve varying levels of success. For example, the special technical feature of Condition caused by axonal damage caused by concussion, is not shared by the other Conditions caused by damage to the CNS.

**D) Conditions caused by defect to the CNS**

The species are listed in claims 33-34 as follows:

Memory loss, multiple sclerosis, asphyxia,.....demyelinating disorder

**If applicant elected the ‘Conditions caused by defect to the CNS’ group as the species of Condition, applicant is further required to select a more specific Condition caused by defect to the CNS.**

The claims are deemed to correspond to the species listed above in the following manner: Claim 33-34

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above disorders associated with a defect of the CNS have distinct pathology and the treatment would

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involve varying levels of success. For example, the special technical feature of Memory loss is not shared by the other conditions caused by defect to the CNS.

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. In response to this Office Action/Election requirement, applicant must elect one from Groups I-VI and must additionally elect a species of loss or gain of cell type/nervous tissue, condition, conditions caused by damage to the CNS and conditions caused by defect to the CNS.

6. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if



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one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(l).

***Advisory Information***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037.

The examiner can normally be reached on M-F.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD

14 April 2008

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649